

Appl. No. : 09/782,534  
Filed : February 13, 2001

## **REMARKS**

Claims 6, 8-11, 15-17, 19, 21, 23, 24, 26, 27, 32, and 45-47 were previously cancelled, without prejudice. In the Office Action mailed August 23, 2004, the Examiner withdrew from consideration Claims 7, 12-14, 18, 20, 22, 25, 28-31, 33-44, and 50-52. In the April 20, 2005 Office Action the Examiner acknowledged that Claim 1 has been amended but maintained rejections of Claims 1-5, 48, and 49. In response to the April 20, 2005 Office Action and to facilitate examination of the present application, Applicants have cancelled Claims 7, 18, 20, 22, 25 and 28, without prejudice. Applicants may elect to reintroduce Claims 7, 18, 20, 22, 25 and 28 at a later time.

### Claim Rejections - 35 U.S.C. § 103

In the Office Action mailed April 20, 2005, the Examiner rejected Claims 1-5, 48, and 49 under 35 U.S.C. § 103(a) as being obvious and therefore unpatentable over Reiley et al. (U.S. Patent No. 6,440,138) in light of Simonson (U.S. Patent No. 6,159,179). With regard to Claim 1, the Examiner asserted that Reiley et al. disclose an apparatus comprising all limitations of Claim 1 except a beveled distal end on the anterior tract sheath. The Examiner further asserted that Simonson discloses a “beveled end 20 at the distal end of the tubular body 18 . . . [which] serves to help the insertion of the cannulated retractor 10 entering the body of the patient.” The Examiner contended that it would have been obvious to one with ordinary skill in the art at the time the invention was made to alter the anterior tract sheath of Reiley et al to have a beveled distal end for aiding insertion into a patient’s body, as taught by Simonson.

Applicants respectfully traverse these rejections and the Examiner’s characterization of the cited references in relation to the present application. Applicants’ invention pertains to “An apparatus for cutting material inside an intervertebral disc,” as recited by Claim 1. The beveled distal end of the anterior tract sheath of Claim 1 comprises a distal end cut away at an angle to form an inclined surface having a point at the distal end of the anterior tract sheath. The beveled tip of Claim 1 facilitates: (1) anchoring of the anterior tract sheath and (2) fitted engagement between the inclined distal end of the sheath and the correspondingly inclined anterior surface of a sacral vertebra with respect to the longitudinal axis of Applicants’ transsacral axial, as opposed

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to a lateral, pathway leading to an intervertebral disc. The specification of the present application states “The shaped end 98 of the anterior tract sheath 96 is **aligned with the anterior surface of the sacral vertebra S1 . . .** The shaped end 98 may be formed with attachment teeth or threads to fix it to the sacral bone.” See, e.g., Applicants’ Figures 17 and 18. Amended Claim 1 recites:

1. An apparatus for cutting material inside an intervertebral spinal disc . . . the apparatus comprising:

an anterior tract sheath having a beveled distal end for **engaging an anterior surface of the sacral vertebral body;**

wherein the beveled distal end of the anterior tract sheath **facilitates anchoring** of the anterior tract sheath onto the anterior surface of the sacral vertebral body from a para coccygeal skin access point.

Simonson has nothing to do with a complimentary fit between an access sheath and a surface of the sacrum which is non-normal to the axis of the sheath. To the contrary, Simonson discloses a device used to measure the depth of a body cavity. The distal end of the Simonson device does not come to a point formed by an inclined distal face as described by Applicants, but rather comprises a flat distal end of a cannulated dilator separated from the rest of the dilator by a tapering or beveled section that gives the distal end a smaller outside diameter than the rest of the dilator. The function of the Simonson bevel is to aid in insertion of the device. The Simonson specification states “the cannulated dilator 10 comprises a hollow tubular body 18 . . . having a beveled end 20 at the distal end of the tubular body 18 . . . The beveled at the distal end 20 serves to **help the insertion** of the cannulated retractor 10 entering the body of the patient.” Thus, although Simonson does use the term “beveled,” that merely refers to a thinning of the sidewall of the tube, rather than a diagonal end face as described by Applicants, for cooperating with Applicants’ unique access geometry.

The beveled tip of the anterior sheath of Applicants’ apparatus for cutting inside an intervertebral disc comprises an inclined face which comes to a point distally and facilitates anchoring of the sheath and fitted engagement of the sheath with the inclined anterior surface of a sacral vertebra. As such, Applicants’ beveled tip has little in common with Simonson’s beveled tip, which does not have an inclined distal surface but is flat at its distal end, and which aids in the insertion of a depth-measuring device. Nothing in the Simonson disclosure suggests that a beveled tip on an anterior sheath could be used to aid in anchoring the sheath and engaging a vertebral body in an axial path accessing an intervertebral disc.

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There is also no suggestion by Reiley et al. of using a beveled tip on an anterior sheath for anchoring and engaging a vertebral body as described by Applicants. Furthermore, Reiley et al. disclose cutting of material inside an intervertebral disc which is accessed laterally, not axially as described by Applicants. Thus, there is no motivation for one skilled in the art to combine Simonson's beveled tip with the apparatus for cutting inside an intervertebral disc of Reiley et al. Accordingly, Applicants respectfully submit that the teachings of Reiley et al. and Simonson fail to establish a *prima facie* showing of obviousness, and the rejection should therefore be withdrawn.

Claims 2-5, 48, and 49, which depend from Claim 1, are believed to be patentable for the reasons stated above with respect to Claim 1, and because of the additional limitations set forth therein. Applicants respectfully submit that Claims 1-5, 48, and 49 would not have been obvious under 35 U.S.C. § 103(a) and are patentable over Reiley et al. in light of Simonson. Accordingly, Applicants respectfully request that the rejection of Claims 1-5, 48, and 49 be withdrawn.

In view of the foregoing, Applicant respectfully submits that the pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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